Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

MANUFACTURER OF CONTROLLED SUBSTANCES

NOTICE OF APPLICATION

CAMBREX CHARLES CITY, INC.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 25 2013, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine	
(8333)	II
Phenylacetone (8501)	II
Cocaine (9041)	II

Drug	Schedule
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR § 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION].

Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control Drug Enforcement Administration

DATED: September 27, 2013

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